

PSJ3

Exhibit 197

THE PAIN & POLICY STUDIES GROUP

University of Wisconsin
Comprehensive Cancer Center
School of Medicine and Public Health
*World Health Organization Collaborating Center
for Policy and Communications*

Prospectus

The University of Wisconsin Pain and Policy Studies Group is seeking support for its program to evaluate and respond to analgesic policy issues in the U.S. and to improve the regulatory environment for pain management.

Background

Although there is a medical and scientific consensus in the U.S. that opioid analgesics must be readily available to effectively manage pain due to cancer and other chronic diseases, fear of opioids and an uncertain regulatory environment impedes adequate pain relief. Decades of anti-drug abuse campaigns have communicated misinformation about opioids and have given little attention to their medical uses. Although the study and treatment of pain as a relatively new area of medical science is advancing, the regulatory environment continues to be a very important issue.

The rate of growth in pain management will depend to some degree on whether the barriers including those related to regulation of opioids and controlled substances can be overcome. These barriers include lack of knowledge and uninformed attitudes about pain and pain medications among regulators and policy makers. These barriers also include a number of drug-related policies.

The prescription of opioid analgesics is strictly governed by federal and state anti-drug abuse laws and regulations, many of which were adopted before the advent of new medical and scientific knowledge about pain and opioids. Some of these policies have the unintended effect of interfering, directly or indirectly, with the use of opioids in medical practice and patient care. Although there is some improved understanding of the advances in knowledge regarding pain, pharmacology and addiction, many still have beliefs that are based upon outdated information.

Consequently, those who wish to improve the management of pain in the community, and in hospitals, hospices, home care and long-term care facilities, face the challenge of identifying and modifying public policy and educating regulators and policy-makers.

Qualifications

The Pain and Policy Studies Group is part of the University of Wisconsin Comprehensive Cancer Center in the UW School of Medicine and Public Health. The Director is David Joranson, a former drug regulator, co-founder of the Wisconsin Cancer Pain Initiative, and an authority on national and international pain and opioid policy matters. The staff members of the PPSG have

academic degrees in fields related to policy; they are experts with years of experience in the U.S.; they have excellent relationships with key organizations; and they have published widely. The PPSG is a World Health Organization Collaborating Center for Policy and Communications in Cancer Care. PPSG's mission, vision, and program in the U.S. is predicated on the realization that evidence-based policy and communications are essential for the advancement of pain and palliative care.

Vision

Our vision is that pain management will be adequately available when and where it is needed so that people who suffer pain from cancer, AIDS, surgery, accidents, and chronic conditions will have relief from their pain, improved functioning and a better quality of life.

Mission

Our mission is to promote "balance" in international, national and state pain policies to ensure adequate availability of opioid analgesics and their appropriate medical use for patient care while addressing diversion and abuse; and to support a communications program to improve access to information about pain relief, palliative care, and pain policy.

Program

A. Policy research

The PPSG research program is targeted at questions that are strategically important to the pain and palliative care field, such as the trends in medical use and abuse of prescription pain medications, the influence of policies and other events on opioid use and professional practice; trends in knowledge and attitudes of regulators and implications for practice; the extent of diversion of pain medications, the significance of source and implications for law enforcement, medicine and pharmacy policy. PPSG maintains major longitudinal databases describing diversion, abuse and consumption of opioid analgesics in the U.S. PPSG staff members review newly-published literature regularly, and maintain an extensive reference database.

B. Policy evaluation

The PPSG policy evaluation program has several components. PPSG developed a methodology to evaluate federal and state policies according to the principle of "balance" which recognizes that policies aimed at preventing drug abuse must not interfere with medical practice and patient care. PPSG publishes State Profiles that identify provisions in each state that have the potential to enhance or impede pain management. The Profiles are designed to be used in developing plans of action to improve the regulatory environment for pain management. The Guides are increasingly used by government and non government organizations to study and revise state policies. PPSG assigns grades to each state to draw attention to the need to improve pain policy and to provide an evaluation framework that allows for consistent benchmarking of progress over time. A Progress Report Card compared the policies in 2003 with those in 2000 and found that many states had improved the degree of balance in their pain and regulatory policies. PPSG identifies and

recommends “best” or model policies and assists in their development. PPSG maintains several longitudinal policy data bases that describe the frequency, types, variability and changes in federal and state pain policies over time.

C. Communications

The PPSG Communications program includes publishing, education, internet access, dissemination and technical assistance. PPSG research projects are regularly published in peer reviewed journals, and the Group is frequently invited by federal, national and state organizations to present its research at conferences and meetings. The PPSG public access website is visited frequently as a rich source of information, including most of its research publications and a full text data base of each state’s policies. Periodically, PPSG emails updates on new publications and important policy developments to an extensive list of health and regulatory professionals. PPSG provides rapid responses to requests for information and has provided extensive technical assistance to federal and state organizations who are working to achieve more balanced policies. PPSG research is augmented by an extensive in-house library of current and historical literature pertaining to controlled substances and medical practice policy.

D. Accomplishments: 2004-2005

-- PPSG co-authored a Frequently Asked Questions (FAQ) answering 30 pain management, prescribing and regulatory questions for healthcare professionals, regulators, and law enforcement. The document was reviewed by a multidisciplinary panel of experts, included the DEA as a co-author. In the months following its release and dissemination, and communication, PPSG met with DEA to discuss implementation. DEA abruptly withdrew its support of the FAQ and issued an Interim Policy Statement in the *Federal Register* stating that the FAQ contained “mis-statements:” http://www.deadiversion.usdoj.gov/faq/pain_meds_faqs.htm

PPSG submitted a response to the Interim Policy Statement and to DEA’s request for comments: <http://www.medsch.wisc.edu/painpolicy/DEA/index.htm>

-- PPSG published a re-assessment of ARCOS and DAWN data (following its first article reviewing this subject that was published in JAMA in 2000) to update recent trends in the medical use and abuse of opioid analgesics indicated for severe pain, placing the findings in the context of balance and providing an extended discussion about diversion: Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997-2002. *Journal of Pain & Symptom Management*. 2004; 28(2):176-188. <http://www.medsch.wisc.edu/painpolicy/publicat/04jpsm/04jpsm.pdf>

-- PPSG co-authored a review article about recent developments in California’s prescription monitoring program: Fishman SM, Papazian JS, Riches PS, Gilson AM. Regulating opioid prescribing through prescription monitoring programs: Balancing drug diversion and treatment of pain. *Pain Medicine*. 2004; 5(3):309-324.

-- PPSG co-authored an article describing the Connecticut Medical Board’s adopting a recent policy promoting the appropriate use of controlled substances for pain management, to communicate this policy development to licensees: Hargus E, Trotta P, Gilson A, Ross Russell D,

Sullivan Dinnan M. The medical examining board speaks on pain management: Everyone should listen. *Connecticut Medicine*. 2005; 69(8):487-493.

-- PPSG published an article statistically evaluating the variability, quality, and changes in state pain policies from 2000 to 2003: [Gilson AM, Maurer MA, Joranson DE. State policy affecting pain management: Recent improvements and the positive impact of regulatory health policies. Health Policy. 2005; 74\(2\):192-204.](#)

-- PPSG published an article that describes the policy evaluation methodology and findings from the *Evaluation Guide 2000*, the *Evaluation Guide 2003*, and the *Progress Report Card*: [Gilson AM, Joranson DE, Maurer MA, Ryan KM, Garthwaite JP. Progress to achieve balanced state policy relevant to pain management and palliative care: 2000-2003. Journal of Pain & Palliative Care Pharmacotherapy. 2005; 19\(1\):7-20.](#)

-- PPSG played a central role in revising the Federation of State Medical Board's *Model Guidelines on the Use of Controlled Substances for Pain Management*, now entitled *Model Policy for the Use of Controlled Substances for Pain Management*: http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/2004_model_pain_policy.asp

-- PPSG, in collaboration with the Federation of State Medical Boards, conducted a third national survey of state medical board members' knowledge and attitudes about pain management and public policy to evaluate the current regulatory environment for pain management; initial survey results were used to inform the curricula for a series of educational workshops for medical and pharmacy board members and investigators (see <http://www.medsch.wisc.edu/painpolicy/publicat/01jpsm/index.htm> as an example of our previous work in this area).

--PPSG worked with the Federation of State Medical Boards to develop and present an educational program for five more workshops for state medical board members held across the U.S.; PPSG staff served as faculty, and administered a pre- and post-test survey to evaluate changes in knowledge and attitudes as a result of workshop participation.

-- PPSG is collaborating with the Federation of State Medical Boards to conduct a fourth national survey of state medical board members' knowledge and attitudes about pain management and public policy to evaluate effects of the current regulatory environment on board members' attitudes about the use of pain medications.

-- PPSG worked extensively with several state initiatives, including Divisions of the American Cancer Society, to provide technical assistance for their efforts to improve the degree of balance in state policies (Arizona, California, Connecticut, Montana, New Hampshire, New Mexico, North Dakota, Pennsylvania, Rhode Island, and Texas).

-- PPSG published a research letter about findings obtained from DEA data, resulting in the first study on the extensive non-medical diversion of pain medications from manufacturers, distributors and pharmacies: [Joranson DE, Gilson AM. Drug crime is a source of abused pain medications in the United States. Journal of Pain & Symptom Management. 2005; 30\(4\):299-301.](#)

-- PPSG staff served on the *NIH Center for Substance Abuse Treatment Project on Co-Occurring Disorders, Drug Interactions, and Emerging Issues in Opioid Addiction Treatment*, a project designed to address methadone-associated mortality; PPSG is a continuing member of the Data Working Group that focuses on the extent that current national and state databases can determine the frequency of methadone involvement in abuse episodes and identify the source of drug.

-- PPSG updated the full text database of all state pain policies on its website: <http://www.medsch.wisc.edu/painpolicy/matrix.htm>. This free access website is used frequently by many physicians (who often do not know there is a policy in their state), pain advocates, and company representatives. Information about our website is provided to numerous physicians by experts who give lectures.

-- PPSG published to its website a compendium of the full text of all state laws requiring or encouraging the inclusion of pain and palliative care in professional and continuing medical education. See <http://www.medsch.wisc.edu/painpolicy/domestic/cme.htm>

-- PPSG gave invited presentations to a number of organizations, including

- the American Medical Association Council on Scientific Affairs
- National Conference of State Legislatures
- the 2005 Decade of Pain lecture to the American Pain Society annual scientific meeting
- Mayday Fellows in Pain and Society
- Pharmacist Society of Wisconsin
- training seminar for Assistant Attorneys General sponsored by the National Association of Attorneys General

-- PPSG communicated important developments and new products to an extensive email notification list, with a direct link to the product.

--PPSG provided posters, presentations, or technical assistance to a number of organizations, including

- American Academy of Hospice and Palliative Medicine
- American Alliance of Cancer Pain Initiatives
- American Cancer Society
- College on Problems of Drug Dependence
- Federation of State Medical Boards
- Kaiser Health Systems
- National Hospice and Palliative Care Organization
- Ohio Legislators Cancer Caucus
- Open Society Institute
- Pain Care Forum
- Pharmacist Society of Wisconsin
- Wisconsin Hospice Association
- Women in Government

-- PPSG participates as a member of the Cancer Control Leadership Institute and is assisting in the development of an educational module concerning pain medications and palliative care for state cancer control leadership.